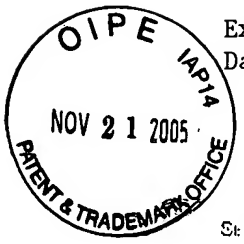

Exp. Mail No.: EV695511326US
Date of Dep: November 21, 2005

Attorney Docket No. 21534-002 CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	Haines et al.		
SERIAL NUMBER	10/621,802	EXAMINER :	Fay, Zohreh A.
FILING DATE	July 16, 2003	ART UNIT :	1614
FOR	ANTI-INFLAMMATORY FORMULATIONS		

Boston, Massachusetts

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450

Alexandria, VA 22313-1450

DECLARATION OF GEORGE OUSLER III UNDER 37 C.F.R §1.132

I, George W. Ousler III, declare and state as follows:

1. I am the Director of the Dry Eye Department at Ophthalmic Research Associates (ORA), a research and development organization for the ophthalmic pharmaceutical and device industry. I hold a bachelor's degree in biology from Trinity College in Hartford, Connecticut, and have been involved in research and management of pre-clinical and clinical evaluation of ophthalmic drugs and devices for over 7 years. I have published extensively on subjects relating to diagnosis and treatment of Dry Eye Syndrome and have held editorial positions on peer-reviewed journals such as Cornea, Survey of Ophthalmology, American Journal of Ophthamology, Ophthamology, Journal of Refractive and Laser Surgery, and Investigative Ophthamology and Visual Sciences.

2. ORA conducted a clinical trial to compare the effects of Dry Eye Oral Supplement (carotenoid/polyphenol composition co-administered with an omega fatty acids composition developed by the inventors and claimed in the above-referenced patent) and a Multivitamin Placebo (a vitamin/mineral supplement that does not contain omega fatty acids). The results of the trial are summarized in the accompanying Declaration of Steven G. Pratt.

3. As Director of the Dry Eye Department of ORA, I have designed, managed, and provided direct oversight of studies to evaluate numerous treatment approaches for relief of signs and symptoms of Dry Eye Syndrome using a Controlled Adverse Environment (CAE) model that my company developed in conjunction with the Food and Drug Administration. This model has been accepted by the FDA as a reliable method for evaluating treatments for Dry Eye Syndrome and has been used in numerous studies that have been published in peer-reviewed journals. In this model, subjects are exposed to standardized conditions such as a humidity level of less than or equal to 10%, temperature of 76°F ± 6°F, constant non-turbulent mild air flow, standard lighting, and are asked to perform a visual task (e.g., watching a movie). Symptoms of Dry Eye are evaluated by asking subjects to assess the level ocular discomfort (perception of grittiness, foreign body sensation, burning/stinging) on a scale of 0-4 prior to entering a CAE room and then every 5 minutes during the 90 minute exposure to CAE.

4. Co-administration of a carotenoid/polyphenol together with omega fatty acids in the form of Dry Eye Oral Supplement provided a remarkable reduction in Dry Eye symptoms during

CAE compared to Multivitamin Placebo. Surprisingly, even the level of mean ocular discomfort at time point zero (i.e., prior to exposure to CAE) of each CAE session improved with the length of administration of Dry Eye Supplement, a result not seen with any other treatment. Among all the therapeutic approaches evaluated under my supervision, the Dry Eye Oral Supplement was overwhelmingly better than any other treatment for reduction of symptoms of Dry Eye using the CAE model.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 11/15/05

George W. Ousler III

Formatted: Font: 9 pt